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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	DEXCOM.008DV1	3546

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
06/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/447,227	SHULTS ET AL.	
	Examiner	Art Unit	
	ROBERT L. NASSER	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,34,38,41,42,48,49 and 54-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33, 34, 38, 41, 42, 48, 49, 54-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/21/2008 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33, 34, 48, 70-78, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khan 5387327 in view of Picha. Khan shows a wholly implantable glucose sensing method including wholly implanting a device in the tissue of a host, where the device provides continuous glucose sensing and comprises a housing 12 with a flat end and a protruding rounded tip 15 having a convexly curved portion that has a different curvature than the housing, where the tip includes a sensing membrane. It does not have the first domain. However, Picha teaches that it is known to encase an implanted sensor in a layer that is angiogenic or promotes vascularization, to

enhance the measurement process, as described in columns 5 and 6. Hence, it would have been obvious to modify Khan to use such a layer, to improve the measurement process. Claim 48 is rejected in that there is an enzyme membrane. With respect to claims 70-72, it is the examiner's position that given that the device of the combination has an angiogenic or vascular promoting layer, it would measure glucose accurately for the claimed time periods. With respect to claims 73-75 the examiner notes that it is well known to explant the device when the useful life of the device is over. Claim 76 is rejected in that the layer of the combination would stabilize, as recited. Claim 77 is rejected in that the foam of Picha is a silicone elastomer (see column 3, line 61). Claim 66 is rejected in that the device is a non-enzymatic sensor (see column 9, lines §-10). With respect to claims 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Allen to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another. Claims 70-78, and 80-83 are rejected for the reasons given above.

Claims 33, 34, 48, 54, and 70-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al 5165407in view of Picha. Wilson shows a wholly implantable glucose sensing method including wholly implanting a device in a host, where the device provides continuous glucose sensing and comprises a housing having a first portion and a protruding tip portion, where the tip is covered with a sensing membrane 24. The tip and other housing portion are both flat. However, the examiner takes official notice that it is known to round edges on implantable devices to minimize

any trauma cause by the edges. Hence, it would have been obvious to provide a rounded tip in Wilson, to eliminate any trauma for the patient. It does not have the first domain. However, Picha teaches that it is known to encase an implanted sensor in a layer that is angiogenic or promotes vascularization, to enhance the measurement process, as described in columns 5 and 6. Hence, it would have been obvious to modify Khan to use such a layer, to improve the measurement process. Claims 48 is rejected in that the sensing membrane includes an enzyme. Claim 54 is rejected in that there is an electrolyte between the sensor and the membrane. With respect to claims 70-72 and 76, it is the examiner's position that given that the device of the combination has an angiogenic or vascular promoting layer, it would measure glucose accurately for the claimed time periods. With respect to claims 73-75, the examiner notes that it is well known to explant the device when the useful life of the device is over. Claim 77 is rejected in that the foam of Picha is a silicone elastomer (see column 3, line 61). Claim 79 is rejected in that the device is an enzymatic sensor (see column 9, lines 5-10). With respect to claims 80-83 the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Wilson to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 38, 41, 42, 49, and 56-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh et al 5914026 in view of Picha. Blubaugh shows a device in figure 4 with a convexly curved housing 54 and a sensor capable of continuous sensing, a membrane 56 over the curved portion, where the sensor is in contact with

the curved portion. It does not have the vascularization promotion layer. However, Picha teaches that it is known to encase an implanted sensor in a layer that is angiogenic or promotes vascularization, to enhance the measurement process, as described in columns 5 and 6. Hence, it would have been obvious to modify Blubaugh to use such a layer, to improve the measurement process. The device is sized for being wholly implanted. With respect to claim 42, the examiner takes official notice that it is well known to wireless transmit data to the exterior in an implantable device. Hence, it would have been obvious to modify the combination to use such a transmitter, as it is merely the selection of a well known design characteristic in the art. Claim 49 is rejected in that there is an enzyme in the sensing membrane. With respect to claims 56-58 and 62, it is the examiner's position that given that the device of the combination has an angiogenic or vascular promoting layer, it would measure glucose accurately for the claimed time periods. With respect to claims 59-61, the examiner notes that it is well known to explant the device when the useful life of the device is over. Claim 63 is rejected in that the foam of Picha is a silicone elastomer (see column 3, line 61). Claim 65 is rejected in that the device is an enzymatic sensor (see column 9, lines 5-10). With respect to claims 66-69 the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Wilson to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claim 55 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh et al 5914026 in view of Picha, as applied to claims 38, 41, 42, 49, and 56-69

above, further in view of Rhodes WO 92/13271. Rhodes further teaches an alternate membrane assembly that has an electrolytic layer. Hence, it would have been obvious to modify the combination to use such a membrane with an electrolyte layer, as it is merely the substitution of one known equivalent membrane for another.

Applicant's arguments filed 3/21/2008 have been fully considered but they are not persuasive.

With respect to Khan, applicant has asserted that it cannot be combined with Picha because using a foam like Picha in the bloodstream would harm the patient. However, the examiner notes that in column 1, line 9, Khan teaches it can measure glucose in tissue liquid, i.e. in tissue, not in the bloodstream. Hence, this argument fails.

With respect to Wilson, as modified, it is the examiner's position that the entire protruding portion is a sensing mechanism and hence meets the claim language.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/

Primary Examiner

Art Unit 3735